DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2014

Spinal Surgical Strategies, LLC
% Mr. Tim Reeves
Regulatory Consultant
999 Driver Way
Incline Village, Nevada 89451

Re: K142661
Trade/Device Name: Bi-Portal Bone Graft Delivery Device
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: September 15, 2014
Received: September 18, 2014

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142661

Device Name: Bi-Portal Bone Graft Delivery Device

Indications for Use:

The Bi-Portal Bone Graft Delivery Device is intended to be used for the delivery of hydrated allograft or autograft to an orthopedic surgical site.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tab 5

Premarket Notification [510(k)] Summary

Submission Date:	September 15, 2014
Trade Name:	Bi-Portal Bone Graft Delivery Device
Common Name:	Piston Syringe
Classification:	21 CFR 880.5860; Class II
Product Code:	FMF
Manufacturer's Name:	Spinal Surgical Strategies, LLC
Address:	999 Driver Way Incline Village, NV 89451
Corresponding Official:	Tim Reeves
Title:	Regulatory Consultant
Address:	c/o Spinal Surgical Strategies 999 Driver Way Incline Village, NV 89451
Telephone:	408-702-7259
Predicate Device:	K121476 - Infill™ Graft Delivery System (Pinnacle Spine Group, LLC)

Indication for Use:

The Bi-Portal Bone Graft Delivery Device is intended to be used for the delivery of hydrated allograft or autograft to an orthopedic surgical site.

Device Description:

The Bi-Portal Bone Graft Delivery Device is comprised of a 21.0 cm length rectangular syringe barrel for surgical site access and bone graft material delivery; a compatible

syringe plunger for pushing the allograft or autograft into the operative site; and, an attachable funnel reservoir for loading prepared material. The barrel has an 8.0 mm by 12.0 mm closed-end tapered distal shaft with a pair of longitudinal bilateral ejection holes near the distal end for material effusion into the surgical space. The barrel can be partially filled with up to 4.0 cc of material and refilled in-situ using the attachable funnel.

When used as an ancillary device to orthopedic surgical procedures that require the placement of autograft or allograft, the Bi-Portal Device can deliver a prepared amount of material. There are no luer lock components to the Device. The bi-portal design is intended to result in graft material effusion through the two laterally placed sideholes. This allows the material to be selectively placed within the surgical space adjacent to the Device barrel tip.

Performance Testing:

Testing has been performed to support safety and effectiveness to the predicate and to demonstrate performance as intended. The Bi-Portal Bone Graft Delivery Device was verified by bench evaluation for simulated use, pressure-force, leak test and shaft strength.

Biocompatibility:

The Bi-Portal Bone Graft Delivery Device is composed of sterile medical grade plastic components, which has passed all of the recommended biocompatibility test requirements of ISO 10993-1.

Sterilization and Packaging:

Sterilization validation, package integrity, distribution simulation and shelf life studies were completed and documented for the Bi-Portal Bone Graft Delivery Device. Studies were conducted in accordance with the applicable recommendations from the FDA Piston Syringe and 510(k) Guidance documents, and the applicable recognized standards. All test acceptance criteria were met.

The Device is labeled sterile, for single-use only. The packaging and contents are ethylene oxide sterilized by a validated process to a Sterility Assurance Level (SAL) of 10^{-6} per ANSI/AAMI/ISO 11135-1 for ethylene oxide sterilization of health care products Accelerated aging was completed to support a labeled shelf life of 12 months.

Substantial Equivalence

The Bi-Portal Bone Graft Delivery Device was evaluated in accordance with 21 CFR 807.87(d - g) to verify substantial equivalence. The intended use of the Device is the same as the predicate device. The comparison table provides an overview of the key features, indications and technological comparisons of the Device to the 510(k) predicate. Predicate device information has been obtained through the respective 510(k) summary and labeling information provided by the manufacturer. These comparisons support substantial equivalence for the technology, function, mechanism of action and intended use to the predicate. There are no new type safety or effectiveness questions for the Bi-Portal Bone Graft Delivery Device to the stated indication for use.

Comparison Table: Substantial Equivalence Comparison of Bi-Portal Bone Graft Delivery Device to the Predicate Device for Bone Graft Delivery

Manufacturer; Device / **Attributes**	**Spinal Surgical Specialties; Bi-Portal Bone Graft Delivery Device**	**Pinnacle Spine Group; Infill™ Graft Delivery System (*K121476*)**
Product Code; Common Name	FMF; Piston Syringe	
Classification	Class II; 21 CFR 880.5860	
Indication for Use	The Bi-Portal Bone Graft Delivery Device is intended to be used for the delivery of hydrated allograft or autograft to an orthopedic surgical site.	The InFill™ Graft Delivery System is intended to be used for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site.
Intended Use	Bone graft delivery to an orthopedic surgical site.	
Mechanism of Action	Graft Material dispersed from device tip by depressing the plunger.	
Graft Injection	Bilateral sidehole delivery into surgical space.	Endhole delivery into surgical space and instrumentation.
Syringe Material	Biocompatible Medical Grade Plastics	
Syringe Components	Barrel, Plunger and Funnel	Barrel, Plunger, Stylet, Cannula extension and Funnel
Bone Graft Exit Hole Diameter	Two sideholes: 5.6 mm x 14.8 mm	Single cannula endhole: 8.0 mm
Recommended Graft Volume	Up to 4.0 cc in Barrel	Up to 4.0 cc in Cannula
Sterility	Yes; Single Use Only	